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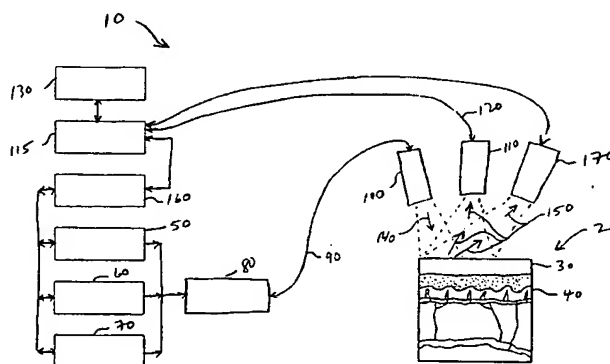
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(54) Title: **PHOTOSTIMULATON TREATMENT APPARATUS AND METHODS FOR USE**



(57) Abstract: A therapeutic treatment apparatus (10) for photostimulation of biological tissue (20, 30, 40) that includes at least one treatment radiation source source (50) configured to radiate energy at a predetermined wavelength selected from the range approximately between 400 and 1,500 nanometers and adapted to illuminate the biological tissue (20, 30, 40). The apparatus further incorporates an infrared camera (110) configured to detect infrared radiation and adapted to produce image signals corresponding to the detected radiation. A data processing and recording device (115) is also included that is capable of receiving and processing the image signals and is adapted to generate an electronic signal in the form of a plurality of frames corresponding to the image signals. The data processing and recording device (115) is also configured to capture and analyze the frames to quantify the radiation emitted by the biological tissue in units of measurement selected from the group including wavelength, radiance, luminosity, area, volume, temperature, change in temperature, rate of change of temperature, relative temperature, energy, change in energy, rate of change of energy, and relative energy. The data processing and recording device (110) is also configured to detect, block, and/or subtract the energy emitted from the radiation source (50) that is reflected by the target (20, 30, 40) when quantifying the energy emitted by the biological tissue (20, 30, 40) sans the reflected energy. A method for using the device (10) is also described.

PHOTOSTIMULATION TREATMENT APPARATUS AND METHODS FOR USE**Technical Field**

This invention relates to an apparatus for treating various biological tissues and biomedical conditions in mammals with a photostimulation device that is precisely controlled
5 using, in part, a high-precision temperature monitoring device such as a thermographic diagnostic device.

Background of the Invention

The treatment of various biomedical conditions in mammals have been treated by
10 physicians and therapists using a wide variety of photostimulation devices. Many such devices are configured to emit radiation having visible and infrared wavelengths (approximately between 400 to 11,500 nanometers) as it has been shown that therapeutic benefits may result from irradiating biological tissue with certain wavelengths of radiation for various periods of time. In various surgical applications, photostimulation devices are configured to emit radiation
15 outside the visible and near-infrared ranges described above to induce photoablation of various tissues, which, depending upon the type of resulting effect, is also referred to by those with skill in the art as ablation, vaporization, ionization, and destruction. In both surgical and therapeutic applications, various attempts have been made to monitor the temperature of the biological tissues subject to the incident radiation so that minimum and maximum energy input to the
20 biological tissues can be induced and/or maintained.

In any application of photostimulation techniques to biological tissue, various incident radiation parameters are to be selected, adjusted, and monitored including the wave length, energy, pulse duration (including a continuous pulse), divergence of the incident radiation beam, and luminosity. In the past, a wide variety of focusing and defocusing optics have been used to establish a quantified cross-sectional area of the incident radiation beam at the point along a beam axis that intersects the upper surface of the biological tissue. By selecting, monitoring, and controlling at least these parameters, then the user can control the effects on the target biological tissue from the incident radiation, which effects include thermal effects such as vaporization, ionization, heating by phonon absorption, and atomic and molecular electronic, rotational, and vibrational excitation.

In therapeutic applications, it is desirable to induce only so much energy of a selected wavelength on the biological tissue whereby certain desirable effects can be induced. These effects typically do not irradiate the target with enough energy to cause vaporization and/or ionization. However, in most therapeutic applications, the biological tissue is irradiated with enough energy to induce the desired therapeutic effect, which can include photocoagulation as well as less damaging thermal effects such as denaturing of the tissue proteins. Even less damaging effects can also be initiated that include photostimulated biochemical changes induced by electronic, rotational, and vibrational excitation of the various constituents of the target biological tissue. At least one study has attempted to classify the various optical properties of human tissue. See, e.g., p. 1386, Parrish, J.A., Deutsch, T. F., *Laser Photomedicine*, I.E.E.E. J. of Quantum Electronics, Vol. QE-20, No. 12, 12/1984; Meyer, R. A., et al., *A Laser Stimulator for the Study of Cutaneous Thermal and Pain Sensation*, I.E.E.E. Transactions on Biomedical Engineering, Vol. BME-23, No. 1, pp. 54-60, 1/1976; *A Brief Report, and Some Abstracts from the International Discussions of Laser Applications in*

Medicine, Paris, 7-8 July 1969, Medical and Biological Engineering, Vol. 8, pp. 427-430, Pergamon Press, 1970, Great Britain.

Various photostimulation devices have been taught in the prior art that are configured for irradiating and/or ablating target biological tissue. U.S. Pat. No. 5,346,488 to Prince et al. is limited to ablation of atherosclerotic plaque using short-duration laser pulses. U.S. Pat. Nos. 5,112,328; 5,196,004; 5,520,697; and 5,540,676 are directed to laser-based surgical devices that incorporate one or more laser radiation sources emitting electromagnetic radiation having one or more wavelengths and which are adapted to be used in various photomedicinal applications. U.S. Pat. No. 5,150,704 is directed to a device that incorporates multiple radiation sources for irradiating selected body parts with a plurality of laser probes. U.S. Pat. Nos. 4,854,320 and 5,002,051 are both limited to irradiation of laser energy to cause the denaturing of collagenous proteins of biological tissue to produce a biological glue to purportedly improves healing of wounds. Other examples of laser-based photostimulation devices configured for use in a variety of surgical and therapeutic applications include U.S. Pat. Nos. 4,573,465; 4,966,144; 5,161,526; 5,409,482; 5,445,146; 5,527,350; and 5,951,596; French Pat. Nos. 2,458,272; 2,561,515; 2,577,425; German Pat. Nos. 2,820,908; 3,401,492; and U.S.S.R. Pat Nos. 871,802; 1,242,187; 1,771,762; and 1,782,617.

None of these references disclose, teach, suggest, or provide any motivation for incorporating energy management devices that can precisely measure the actual amount of energy absorbed by the target biological tissue. In the applications described in the prior art where certain predetermined dosages of energy were to be applied to the target biological tissue, the radiation source and the method of its use to irradiate the target biological tissue was preconfigured to operate at a preselected wavelength, energy output, pulse rate, frequency, and/or exposure time.

Various types of temperature measuring devices exist. However, very few of the temperature measurement devices available in the prior art are suitable for use for purposes of the present invention. The prior art describes various types of temperature measurement devices. In most applications, surface contact thermistors and/or thermometers are used to measure the surface temperature of the target biological tissue. However, these types of devices are unsuitable for purposes of the present invention because they cannot be moved in real-time in applications where the target biological tissue includes a wide area that is irradiated in sections that are changed or rotated over some time interval. Additionally, the presence of a contact temperature measurement can interfere with the desired irradiation treatment modality.

U.S. Pat. Nos. 5,115,815; 5,386,117; 5,458,418; 5,467,126; 5,595,444; and 5,637,871 disclose various non-contact devices that are configured to measure the temperature of a target surface using various types of infrared radiation detection devices that operate using well-known thermography principles. Despite the capabilities of the various systems disclosed in the prior art, none the references discloses, suggests, or describes any motivation to use the thermography devices in accordance with the aspects of the present invention.

What has been needed but unavailable in the prior art is the accurate, real-time detection of temperature during treatment of a target biological tissue using surgical and therapeutic photostimulation devices. In particular, what has been needed is a photostimulation device and method for use that can impart a precisely controlled amount of energy to a target biological tissue and that can simultaneously, continuously, and precisely monitor the energy imparted to the target tissue. Accordingly, the present invention discloses an apparatus and a method for use that incorporates these and other capabilities.

SUMMARY OF THE INVENTION

In general, the present invention relates to an apparatus, and a method for using it, that is directed to the photostimulation of biological tissue such as, for example without limitation, cutaneous and subcutaneous biological tissues. Many types of electromagnetic radiation sources, guides, projectors, detectors, and controllers are available that are suitable for purposes of the present invention. The apparatus includes a therapeutic treatment apparatus for photostimulation of biological tissue that includes at least one treatment radiation source that is configured to emit radiation at a predetermined wavelength selected from the range of approximately between 400 and 11,500 nanometers.

The treatment radiation source may be one of a plurality of sources each configured to emit radiation at one or more wavelengths including, for purposes of illustration but not limitation, the above described range. In configurations where more than one treatment radiation source is used, then the sources are preferably coupled to an optical coupler. The coupler is further coupled to a radiation guide such as a fiber optic guide adapted to communicate the radiation of the treatment source or sources.

Preferably, the at least one treatment radiation source is selected from the group including semiconductor laser diodes, super-luminous diodes, light emitting devices, and solid-state laser diodes ("SSD"). More preferably, the at least one treatment radiation source is configured to emit radiation having a wavelength of approximately between 800 and 1,100 nanometers. Even more preferably, the at least one treatment radiation source is a neodymium-yttrium-aluminum-garnet ("Nd:YAG") laser tuned to emit radiation having a wavelength of approximately 1,064 nanometers.

The fiber optic guide may be further connected to a radiation focusing device such as a radiation emitting probe or wand that can be manipulated by a user for purposes of irradiating the target biological tissue. Each of the treatment radiation sources may

alternatively be coupled to additional, independent wands or probes via additional, separate fiber optic cables.

For configurations of the present that employ treatment radiation that is invisible to the unaided human eye, an additional radiation source configured to emit radiation in the visible spectrum may be coupled to the previous treatment radiation sources to operate as an aiming radiation source. Alternatively, the aiming radiation source may be coupled to each of the radiation sources that are independently coupled to separate wands or probes. In other variations, additional aiming radiation sources may be used to emit radiation at various visible wavelengths of light so that multiple aiming radiation wavelengths may be employed and coupled to selected treatment radiation sources. For example, visible blue light may indicate treatment radiation of a first wavelength, while visible red light may be used to indicate a different treatment radiation wavelength, and other colors may be used to indicate other types of treatment radiation. Alternatively, multiple different wavelengths of aiming radiation may be used to indicate modes of operation. For example, power settings below a certain predetermined threshold may be identified by visible red light, while higher power settings may be indicated using visible blue light.

The present invention also incorporates a video-type camera that is preferably configured to detect infrared radiation having a wavelength approximately between 700 and 20,000 nanometers. The camera is further preferably adapted to produce image signals corresponding to the detected radiation. A data processing and recording device is also included in the present invention, which is capable of receiving and processing the image signals and adapted to generate an electronic signal in the form of a plurality of digitally encoded frames corresponding to the image signals. The data processing and recording device preferably captures and analyzes the frames. In analyzing the frames, the data processing and recording device is configured to quantify the radiation emitted by the

biological tissue in units of measurement selected from the group including wavelength, radiance, luminosity, temperature, area, volume, change in temperature, rate of change of temperature, relative temperature, energy, change in energy, rate of change of energy, and relative energy.

5 The data processing and recording device may also include a memory or storage component capable of temporarily and/or permanently storing the image signals, electronic signals, and/or frames to any of a number of such components including, for example but not for limitation, random access memory, floppy disks, CD-ROMs, conventional hard disks, analog or digital video tape, and any other type of readily available storage media that is
10 presently available for such purposes.

 In a variation of the preceding embodiment, the therapeutic treatment apparatus for photostimulation of biological tissue incorporates at least one treatment radiation source providing radiation at a predetermined wavelength selected from the range approximately between 800 and 1,100 nanometers and adapted to illuminate the biological tissue. In a
15 further variation, the data processing and recording device is capable of receiving and processing the image signal and adapted to generate an electronic signal in the form of a plurality of frames corresponding to the image signal at various time intervals. Preferably, the data processing and recording device captures and analyzes the frames to quantify the radiation emitted by the biological tissue in units of measurement selected from the group
20 described above. More preferably, the data processing and recording device is further configured to control the energy output of the at least one treatment radiation source to induce and maintain a preselected energy input to and output from the biological tissue.

 The present invention also contemplates a variation wherein the data processing and recording device is configured to measure the temperature of the biological tissue and to

control the output of the at least one treatment radiation source whereby the biological tissue is heated to and maintained at a predetermined temperature for a selected period of time.

In another variation of the instant invention, the therapeutic treatment apparatus for photostimulation of biological tissue is modified wherein the data processing and recording
5 device is further configured to block the energy emitted by the at least one treatment radiation source that is reflected by the biological tissue and subtract the reflected energy from quantified unit of measure.

The present invention is also directed to a variation wherein the data processing and recording device is further configured to control the energy output of the at least one
10 treatment radiation source to induce and maintain a preselected energy input to and output from the biological tissue sans the reflected energy.

In yet another variation of the present invention, a therapeutic treatment apparatus for photostimulation of biological tissue includes at least one treatment radiation source providing radiation at a predetermined wavelength selected from the range approximately
15 between 400 and 11,500 nanometers and adapted to illuminate the biological tissue. Also included is an infrared camera configured to detect infrared radiation emitted by the target biological tissue and adapted to produce an image signal corresponding to the detected radiation and further including a filter component adapted to block radiation having the predetermined wavelength, the filter selected from the group including optical and electronic
20 filters. This variation further incorporates a data processing and recording device that is capable of receiving and processing the image signal and adapted to generate an electronic signal in the form of a plurality of frames corresponding to the image signal. The data processing and recording device is adapted to capture and analyze the frames to quantify the radiation emitted by the biological tissue in at least one unit of measurement selected from the
25 group including wavelength, radiance, luminosity, area, volume, temperature, change in

temperature, rate of change of temperature, relative temperature, energy, change in energy, rate of change of energy, and relative energy.

In an alternative configuration, the instant invention contemplates a therapeutic treatment apparatus for photostimulation of biological tissue that incorporates at least one treatment radiation source providing radiation at a predetermined wavelength selected from the range approximately between 400 and 11,500 nanometers and adapted to illuminate the biological tissue. This configuration includes an infrared camera configured to detect infrared radiation emitted by the target biological tissue and adapted to produce an image signal corresponding to the detected radiation at windows corresponding to precise moments in time. A data processing and recording device is also incorporated that is capable of receiving and processing the image signal, and which is adapted to generate an electronic signal in the form of a plurality of frames corresponding to the image signal. The data processing and recording device in this alternative configuration is adapted to capture and analyze the frames to quantify the radiation emitted by the biological tissue in at least one unit of measurement selected from the group including wavelength, radiance, luminosity, area, volume, temperature, change in temperature, rate of change of temperature, relative temperature, energy, change in energy, rate of change of energy, and relative energy. This configuration of the data processing and recording device is further modified to control the infrared camera and the energy output of the at least one treatment radiation source to emit pulses of radiation to induce and maintain a preselected energy input to and output from the biological tissue sans the reflected energy. Lastly, the data processing and recording device is further configured to block the detection of treatment radiation reflected by the biological tissue by synchronizing the timing the emitted treatment radiation pulses with the infrared camera detection windows so that the camera captures an image of the radiation emitted by the target biological tissue at a moment between radiation pulses.

The present invention also contemplates a method for use of a therapeutic treatment apparatus for photostimulation of biological tissue that includes the steps of selecting at least one treatment radiation source that provides radiation at a predetermined wavelength selected from the range approximately between 400 and 11,500 nanometers and adapted to illuminate the biological tissue. Also included is the step of selecting an infrared camera that is configured to detect infrared radiation emitted by the target biological tissue, the camera being adapted to produce image signals corresponding to the detected radiation. A data processing and recording device is selected that is capable of receiving and processing the image signals and adapted to generate an electronic signal in the form of a plurality of frames corresponding to the image signals. The data processing and recording device captures and analyzes the frames and also quantifies the radiation emitted by the biological tissue. The radiation is quantified in at least one unit of measurement selected from the group including wavelength, radiance, luminosity, area, volume, temperature, change in temperature, rate of change of temperature, relative temperature, energy, change in energy, rate of change of energy, and relative energy.

In a variation of the preceding method, the method further includes the steps of controlling the energy output of the at least one treatment radiation source to induce and maintain a preselected energy input to and output from the biological tissue; blocking the energy emitted by the at least one treatment radiation source that is reflected by the biological tissue and subtracting the reflected energy from quantified unit of measure; and controlling the energy output of the at least one treatment radiation source to induce and maintain a preselected energy input to and output from the biological tissue sans the reflected energy.

Brief Description of the Drawing

Without limiting the scope of the present invention as claimed below and referring now to the drawings, wherein like reference numerals and numerals with primes across the several views refer to identical, corresponding, or equivalent features and parts:

5 Figure 1 is a schematic representation of the various elements of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The therapeutic treatment apparatus of the present invention is generally configured for photostimulation of biological tissue. The apparatus includes at least one treatment
10 radiation source adapted to radiate electromagnetic energy at a predetermined wavelength selected from the range approximately between 400 and 11,500 nanometers. The apparatus further incorporates an infrared camera configured to precisely and continuously detect infrared radiation. The camera is adapted to produce image signals corresponding to the detected radiation. A data processing and recording device is also included that is capable of
15 receiving and processing the image signals. The data processing and recording device is further adapted to generate an electronic signal in the form of a plurality of digital frames that correspond to the image signals. The data processing and recording device is also configured to capture and analyze the frames and to quantify the radiation emitted by the biological tissue. The radiation is quantified in units of measurement selected from the group including
20 wavelength, radiance, luminosity, temperature, area, volume, change in temperature, rate of change of temperature, relative temperature, energy, change in energy, rate of change of energy, and relative energy. The data processing and recording device is also configured to detect and/or block the energy emitted from the at least one treatment radiation source that is reflected by the target biological tissue. The therapeutic treatment apparatus is also
25 configured to quantify the energy emitted by the biological tissue by blocking or subtracting

the reflected energy from the quantified result. A method for using the device in its multiple configurations, variations, modifications, and alternatives is also disclosed.

Referring now to FIG. 1, the present invention relates to an apparatus 10, and a method for using it, that is directed to the photostimulation of biological tissue 20 such as, for example without limitation, cutaneous and subcutaneous biological tissues 30, 40. Many types of electromagnetic radiation sources, guides, projectors, detectors, and controllers are available that are suitable for purposes of the present invention. Many such devices that include such components are disclosed in co-owned U.S. patent application serial no.

09/281,443, filed on March 29, 1999, now U.S. Pat. No. _____, and in U.S. Pat.

Nos. 4,573,465; 4,966,144; 5,002,051; 5,049,147; 5,112,328; 5,139,494; 5,150,704; 5,445,146; 5,527,350; 5,540,676; 5,755,752; and 5,951,596, each of which are hereby incorporated by reference in their entirety.

The apparatus of the instant includes a therapeutic treatment apparatus for photostimulation of biological tissue that includes at least one treatment radiation source 50 that is configured to emit radiation at a predetermined wavelength selected from the range of approximately between 400 and 11,500 nanometers.

The treatment radiation source 50 may be one of a plurality of sources 50, 60, 70 each configured to emit radiation at one or more wavelengths including, for purposes of illustration but not limitation, the above described range. In configurations where more than one treatment radiation source is used, then the sources 50, 60, 70 are preferably coupled to an optical coupler 80. The coupler 80 is further coupled to a radiation guide 90 such as a fiber optic guide adapted to communicate the radiation of the treatment source or sources.

Preferably, the at least one treatment radiation source 50 is selected from the group including semiconductor laser diodes, super-luminous diodes, light emitting devices, and solid-state laser diodes ("SSD"). More preferably, the at least one treatment radiation source

50 is configured to emit radiation having a wavelength of approximately between 800 and 1,100 nanometers. Even more preferably, the at least one treatment radiation source 50 is a neodymium-yttrium-aluminum-garnet ("Nd:YAG") laser tuned to emit radiation having a wavelength of approximately 1,064 nanometers.

5 The fiber optic guide 90 may be further connected to a radiation focusing device such as a radiation emitting probe or wand 100 that can be manipulated by a user for purposes of irradiating the target biological tissue 20. Each of the treatment radiation sources 50, 60, 70 may alternatively be coupled to additional, independent wands or probes via additional, separate fiber optic cables (not shown).

10 For configurations of the present that employ treatment radiation that is invisible to the unaided human eye, an additional radiation source configured to emit radiation in the visible spectrum, such as for example, source 70, may be coupled to the previous treatment radiation sources 50, 60 to operate as an aiming radiation source. Alternatively, the aiming radiation source 70 may be coupled to each of the radiation sources 50, 60 that are

15 independently coupled to separate wands or probes similar to probe 100. In other variations, additional aiming radiation sources (not shown) may be used to emit radiation at various visible wavelengths of light so that multiple aiming radiation wavelengths may be employed and coupled to selected treatment radiation sources. Alternatively, the radiation emitted by aiming source 70 may be split and coupled to various probes. For example, visible blue light
20 may indicate treatment radiation of a first wavelength, while visible red light emitted by a separate source may be used to indicate a different treatment radiation wavelength, and other colors may be used to indicate other types of treatment radiation. Alternatively, multiple different wavelengths of aiming radiation may be used to indicate modes of operation. For example, power settings below a certain predetermined threshold may be identified by visible
25 red light, while higher power settings may be indicated using visible blue light.

The present invention also incorporates a video-type infrared camera **110** that is preferably configured to detect infrared radiation having a wavelength approximately between 700 and 20,000 nanometers. The camera **110** is further preferably adapted to produce image signals corresponding to the detected radiation. A data processing and recording device **115** is also included in the present invention, which is coupled by signal line **120** to the camera **110** and which is capable of receiving and processing the image signals and adapted to generate an electronic signal in the form of a plurality of digitally encoded frames corresponding to the image signals. The data processing and recording device **115** preferably captures and analyzes the frames. In analyzing the frames, the data processing and recording device **115** is configured to quantify the radiation emitted by the biological tissue **20** in units of measurement selected from the group including wavelength, radiance, luminosity, temperature, area, volume, change in temperature, rate of change of temperature, relative temperature, energy, change in energy, rate of change of energy, and relative energy.

The data processing and recording device **115** may also include a memory or storage component (not shown but known to those with skill in the art) capable of temporarily and/or permanently storing the image signals, electronic signals, and/or frames to any of a number of such components including, for example but not for limitation, random access memory, floppy disks, CD-ROMs, conventional hard disks, analog or digital video tape, and any other type of readily available storage media **130** that is presently available for such purposes.

In a variation of the preceding embodiment, the therapeutic treatment apparatus **10** for photostimulation of biological tissue incorporates at least one treatment radiation source **50** providing radiation at a predetermined wavelength selected from the range approximately between 800 and 1,100 nanometers and adapted to illuminate the biological tissue **20**. In a further variation, the data processing and recording device **115** is configured for receiving and processing the image signal and adapted to generate an electronic signal in the form of a

plurality of frames corresponding to the image signal at various time intervals. Preferably, the data processing and recording device 115 captures and analyzes the frames to quantify the radiation emitted by the biological tissue 20 in units of measurement selected from the group described above. More preferably, the data processing and recording device 115 is further
5 configured to control the energy output 140 of the at least one treatment radiation source 50 to induce and maintain a preselected energy input to and output from the biological tissue 20.

The present invention also contemplates a variation wherein the data processing and recording device 115 is configured to measure the temperature of the biological tissue 20 and to control the output of the at least one treatment radiation source 50 whereby the biological
10 tissue 20 is heated to and maintained at a predetermined temperature for a selected period of time.

In another variation of the instant invention, the therapeutic treatment apparatus 10 for photostimulation of biological tissue 20 is modified wherein the data processing and recording device 115 is further configured to block the energy 140 emitted by the at least one
15 treatment radiation source 50 that is reflected by the biological tissue 20 and subtract the reflected energy 150 from quantified unit of measure.

The present invention is also directed to a variation wherein the data processing and recording device 115 is further configured to control the energy output of the at least one treatment radiation source 50 to induce and maintain a preselected energy input to and output
20 from the biological tissue 20 sans the reflected energy 150. This is accomplished either by configuring the device 115 or by coupling the device 115 with an independent controller 160 configured to communicate with and control the at least one treatment radiation source 50 as well as any additional sources 60, 70. If desired, a visible light video camera 170 may also be

incorporated into the apparatus of the present invention for purposes of monitoring and / or recording operation of the instant invention.

In yet another variation of the present invention, a therapeutic treatment apparatus 10 for photostimulation of biological tissue 20 includes at least one treatment radiation source 50 providing radiation at a predetermined wavelength selected from the range approximately between 400 and 11,500 nanometers and adapted to illuminate the biological tissue 20. Also included is an infrared camera 110 configured to detect infrared radiation emitted by the target biological tissue 20 and adapted to produce an image signal corresponding to the detected radiation and further including a filter component (not shown) adapted to block radiation having the predetermined wavelength, the filter selected from the group including optical and electronic filters. This variation further incorporates a data processing and recording device that is capable of receiving and processing the image signal and adapted to generate an electronic signal in the form of a plurality of frames corresponding to the image signal. The data processing and recording device 115 is adapted to capture and analyze the frames to quantify the radiation emitted by the biological tissue 20 in at least one unit of measurement selected from the group including wavelength, radiance, luminosity, area, volume, temperature, change in temperature, rate of change of temperature, relative temperature, energy, change in energy, rate of change of energy, and relative energy.

In an alternative configuration, the instant invention contemplates a therapeutic treatment apparatus 10 for photostimulation of biological tissue that incorporates at least one treatment radiation source 50 providing radiation at a predetermined wavelength selected from the range approximately between 400 and 11,500 nanometers and adapted to illuminate the biological tissue 20. This configuration includes an infrared camera 110 configured to detect infrared radiation 150 emitted by the target biological tissue 20 and adapted to produce an image signal corresponding to the detected radiation 150 at windows corresponding to

precise moments in time. A data processing and recording device 115 is also incorporated that is capable of receiving and processing the image signal, and which is adapted to generate an electronic signal in the form of a plurality of frames corresponding to the image signal.

The data processing and recording device 115 in this alternative configuration is adapted to
5 capture and analyze the frames to quantify the radiation emitted by the biological tissue 20 in at least one unit of measurement selected from the group including wavelength, radiance, luminosity, area, volume, temperature, change in temperature, rate of change of temperature, relative temperature, energy, change in energy, rate of change of energy, and relative energy.

This configuration of the data processing and recording device 115 is further modified to
10 control the infrared camera 110 and the energy output of the at least one treatment radiation source 50 to emit pulses of radiation 140 to induce and maintain a preselected energy input to and output from the biological tissue 20 sans the reflected energy 150. Lastly, the data processing and recording device 115 is further configured to block the detection of treatment radiation 150 reflected by the biological tissue 20 by synchronizing the timing the emitted
15 treatment radiation pulses with the infrared camera detection windows so that the camera 110 captures an image of the radiation being emitted by target biological tissue 20 at a moment between radiation pulses.

The present invention also contemplates a method for use of a therapeutic treatment apparatus for photostimulation of biological tissue 20 that includes the steps of selecting at
20 least one treatment radiation source 50 that provides radiation at a predetermined wavelength selected from the range approximately between 400 and 11,500 nanometers and adapted to illuminate the biological tissue. Also included is the step of selecting an infrared camera 110 that is configured to detect infrared radiation emitted by the target biological tissue 20, the camera 110 being adapted to produce image signals corresponding to the detected radiation.

A data processing and recording device 115 is selected that is capable of receiving and processing the image signals and adapted to generate an electronic signal in the form of a plurality of frames corresponding to the image signals. The data processing and recording device 115 captures and analyzes the frames and also quantifies the radiation 150 emitted by the biological tissue 20. The radiation is quantified in at least one unit of measurement selected from the group including wavelength, radiance, luminosity, area, volume, temperature, change in temperature, rate of change of temperature, relative temperature, energy, change in energy, rate of change of energy, and relative energy.

In a variation of the preceding method, the method further includes the steps of controlling the energy output of the at least one treatment radiation source 50 to induce and maintain a preselected energy input to and output from the biological tissue 20; blocking the energy emitted by the at least one treatment radiation source 50 that is reflected by the biological tissue 20 and subtracting the reflected energy from quantified unit of measure; and controlling the energy output of the at least one treatment radiation source 50 to induce and maintain a preselected energy input to and output from the biological tissue 50 sans the reflected energy 150.

The present invention establishes a significant advance over the previously known devices and methods and the advance is achieved with improved accuracy, simplicity, and without any significant increase complexity of technology.

Thermography is a preferred technique for detecting soft tissue anomalies occurring in various types of biological tissues. Anomalous tissues often experience an altered blood flow circulation. One of the most prominent indicators of anomalies such as inflammation and other injuries is heat, which is due to increased blood circulation. A medical thermogram is a methodology, which allows the detection of such biological soft tissue anomalies by measuring the surface temperature of the target biological tissue.

Thermography is a noninvasive diagnostic application that uses infrared radiation detection technology to quantify the surface temperatures of the target biological tissue and subjacent structures. By converting thermal emissions into a multi-colored "map" wherein various colors correspond to certain wavelengths of emitted radiation, temperature differences as small as approximately between 0.05 and 0.08 degrees Celsius can be detected. In addition to detecting increased heat radiation of target biological tissues, the thermographic techniques of the present invention also contemplate detection of areas where blood circulation is decreased. This can occur where anomalies exist such as nerve damage, a blood clot, and development of subjacent scar tissue. In these anomalous biological tissues regions, the thermographic image may depict cooler than expected temperatures, such as may be expected in tissues that suffer from the initial stages of atrophy or other form of deterioration. It will be understood by those with skill in the art that pathologies of the cutaneous and subcutaneous structures including, for example, tendons, ligaments may be identifiable through identification of the "hot spots" and "cool spots" that while invisible to the unaided human eye, are prominently revealed by thermography. Such anomalous biological tissues can thus be detected as far in advance as two weeks before the onset of clinically detectable signs of injury and/or anomaly.

Various types of thermographic cameras, signal processing, and analysis equipment are known in the prior art that includes U.S. Pat. Nos. 5,959,444; 5,467,126; 5,637,871; and 5,386,117. Vendors known to have cameras and related equipment that are suitable for purposes of use with the present invention include Sierra Pacific Innovations #2, www.x20.org, 1034 Emerald Bay Rd., Dept. 437, South Lake Tahoe, California; Rod Hall International, Inc., www.rodhall.com, 1360 Kleppe Lane, Sparks, Nevada; Microlytics, Inc., www.endeavorship.com, P.O. Box 2022, Stillwater, Oklahoma; Raytheon Systems Company, www.raytheoninfrared.com, 6380 Hollister Avenue, Goleta, California; Infrared Components

Corporation, www.infraredcomponents.com, 2306 Bleecker Street, Utica, New York; and Indigo Systems Corporation, www.indigosystems.com/cameras.html, 5385 Hollister Ave #103, Santa Barbara, California.

Numerous modifications and variations of the preferred embodiments disclosed herein will be apparent to those skilled in the art. For example, although specific embodiments have been described in detail, those with skill in the art can understand that the preceding embodiments and variations can be modified with various types of treatment radiation sources and thermographic camera and data processing devices for desired compatibility with the wide variety of modalities presently in use for photostimulation of biological tissues. Accordingly, even though only few variations of the present invention are described herein, it is to be understood that the practice of these additional modifications and variations and the equivalents thereof, are within the spirit and scope of the invention as defined in the following claims.

WE CLAIM:

1. A therapeutic treatment apparatus for photostimulation of biological tissue, comprising:

at least one treatment radiation source emitting a predetermined wavelength selected from the range approximately between 400 and 11,500 nanometers and adapted to irradiate the biological tissue;

an infrared camera configured to detect infrared radiation emitted by the target biological tissue and adapted to produce image signals corresponding to the detected radiation;

a data processing and recording device configured for receiving and processing the image signals and adapted to generate an electronic signal in the form of a plurality of frames corresponding to the image signals; and

wherein the data processing and recording device captures and analyzes the frames to quantify the radiation emitted by the biological tissue in at least one unit of measurement selected from the group including wavelength, radiance, luminosity, temperature, change in temperature, rate of change of temperature, relative temperature, energy, change in energy, rate of change of energy, and relative energy.

2. The therapeutic treatment apparatus of Claim 1, wherein the data processing and recording device records only temporarily.

3. The therapeutic treatment apparatus of Claim 1, wherein the data processing and recording device is further configured to quantify the radiation emitted by the biological tissue in units of measurement selected from the group including area and volume.

4. The therapeutic treatment apparatus of Claim 1, wherein the at least one treatment radiation source is selected from the group including semiconductor laser diodes, super-luminous diodes, light emitting devices, and solid-state laser diodes.

5. The therapeutic treatment apparatus of Claim 1, wherein the at least one treatment radiation source is a Nd:YAG SSD laser tuned to emit radiation having a wavelength of approximately 1,064 nanometers.

6. The therapeutic treatment apparatus of Claim 1, wherein the at least one treatment radiation source is configured to emit radiation having a wavelength of approximately between 800 and 1,100 nanometers.

7. A therapeutic treatment apparatus for photostimulation of biological tissue, comprising:

at least one treatment radiation source providing radiation at a predetermined wavelength selected from the range approximately between 800 and 1,100 nanometers and adapted to illuminate the biological tissue;

an infrared camera configured to detect infrared radiation emitted by the target biological tissue and adapted to produce an image signal corresponding to the detected radiation;

a data processing and recording device configured for receiving and processing the image signal and adapted to generate an electronic signal in the form of a plurality of frames corresponding to the image signal at various time intervals;

wherein the data processing and recording device captures and analyzes the frames to quantify the radiation emitted by the biological tissue in at least one unit of measurement

selected from the group including wavelength, radiance, luminosity, temperature, area, volume, change in temperature, rate of change of temperature, relative temperature, energy, change in energy, rate of change of energy, and relative energy; and

wherein the data processing and recording device is further configured to control the energy output of the at least one treatment radiation source to induce and maintain a preselected energy input to and output from the biological tissue.

8. The therapeutic treatment apparatus of Claim 7, wherein the data processing and recording device is configured to measure the temperature of the biological tissue and to control the output of the at least one treatment radiation source whereby the biological tissue is heated to and maintained at a predetermined temperature for a selected period of time.

9. The therapeutic treatment apparatus of Claim 7, wherein the at least one treatment radiation source is selected from the group including semiconductor laser diodes, super-luminous diodes, light emitting devices, and solid-state laser diodes.

10. The therapeutic treatment apparatus of Claim 7, wherein the at least one treatment radiation source is a Nd:YAG SSD laser tuned to emit radiation having a wavelength of approximately 1,064 nanometers.

20

11. The therapeutic treatment apparatus of Claim 7, further comprising:
at least one additional treatment radiation source configured to emit radiation having a wavelength of approximately between 800 and 1,100 nanometers.

12. A therapeutic treatment apparatus for photostimulation of biological tissue, comprising:

at least one treatment radiation source providing radiation at a predetermined wavelength selected from the range approximately between 800 and 1,100 nanometers and adapted to illuminate the biological tissue;

an infrared camera configured to detect infrared radiation emitted by the target biological tissue and adapted to produce an image signal corresponding to the detected radiation;

a data processing and recording device configured for receiving and processing the image signal and adapted to generate an electronic signal in the form of a plurality of frames corresponding to the image signal at various time intervals;

wherein the data processing and recording device captures and analyzes the frames to quantify the radiation emitted by the biological tissue in at least one unit of measurement selected from the group including wavelength, radiance, luminosity, area, volume, temperature, change in temperature, rate of change of temperature, relative temperature, energy, change in energy, rate of change of energy, and relative energy; and

wherein the data processing and recording device is further configured to block the energy emitted by the at least one treatment radiation source that is reflected by the biological tissue and subtract the reflected energy from quantified unit of measure.

13. The therapeutic treatment apparatus of Claim 12, wherein the at least one treatment radiation source is selected from the group including semiconductor laser diodes, super-luminous diodes, light emitting devices, and solid-state laser diodes.

14. The therapeutic treatment apparatus of Claim 12, wherein the at least one treatment radiation source is a Nd:YAG SSD laser tuned to emit radiation having a wavelength of approximately 1,064 nanometers.

5 15. The therapeutic treatment apparatus of Claim 12, further comprising:
at least one additional treatment radiation source configured to emit radiation having a wavelength of approximately between 800 and 1,100 nanometers.

10 16. A therapeutic treatment apparatus for photostimulation of biological tissue, comprising:

at least one treatment radiation source providing radiation at a predetermined wavelength selected from the range approximately between 800 and 1,100 nanometers and adapted to illuminate the biological tissue;

15 an infrared camera configured to detect infrared radiation emitted by the target biological tissue and adapted to produce an image signal corresponding to the detected radiation;

a data processing and recording device configured for receiving and processing the image signal and adapted to generate an electronic signal in the form of a plurality of frames
20 corresponding to the image signal at various time intervals;

wherein the data processing and recording device captures and analyzes the frames to quantify the radiation emitted by the biological tissue in at least one unit of measurement selected from the group including wavelength, radiance, luminosity, area, volume, temperature, change in temperature, rate of change of temperature, relative temperature,
25 energy, change in energy, rate of change of energy, and relative energy;

wherein the data processing and recording device is further configured to block the energy emitted by the at least one treatment radiation source that is reflected by the biological tissue and subtract the reflected energy from quantified unit of measure; and

5 wherein the data processing and recording device is further configured to control the energy output of the at least one treatment radiation source to induce and maintain a preselected energy input to and output from the biological tissue sans the reflected energy.

17. The therapeutic treatment apparatus of Claim 16, wherein the at least one treatment radiation source is selected from the group including semiconductor laser diodes, super-luminous diodes, light emitting devices, and solid-state laser diodes.

18. The therapeutic treatment apparatus of Claim 6, wherein the at least one treatment radiation source is a Nd:YAG laser tuned to emit radiation having a wavelength of approximately 1,064 nanometers.

15 19. The therapeutic treatment apparatus of Claim 16, further comprising:

at least one additional treatment radiation source configured to emit radiation having a wavelength of approximately between 800 and 1,100 nanometers.

20 20. A therapeutic treatment apparatus for photostimulation of biological tissue, comprising:

at least one treatment radiation source providing radiation at a predetermined wavelength selected from the range approximately between 400 and 11,500 nanometers and adapted to illuminate the biological tissue;

an infrared camera configured to detect infrared radiation emitted by the target biological tissue and adapted to produce an image signal corresponding to the detected radiation and further including a filter component adapted to block radiation having the predetermined wavelength, the filter selected from the group including optical and electronic
5 filters;

a data processing and recording device configured for receiving and processing the image signal and adapted to generate an electronic signal in the form of a plurality of frames corresponding to the image signal; and

wherein the data processing and recording device captures and analyzes the frames to
10 quantify the radiation emitted by the biological tissue in at least one unit of measurement selected from the group including wavelength, radiance, luminosity, area, volume, temperature, change in temperature, rate of change of temperature, relative temperature, energy, change in energy, rate of change of energy, and relative energy.

15 21. A therapeutic treatment apparatus for photostimulation of biological tissue, comprising:

at least one treatment radiation source providing radiation at a predetermined wavelength selected from the range approximately between 400 and 11,500 nanometers and adapted to illuminate the biological tissue;

20 an infrared camera configured to detect infrared radiation emitted by the target biological tissue and adapted to produce an image signal corresponding to the detected radiation at windows corresponding to precise moments in time;

a data processing and recording device configured for receiving and processing the image signal and adapted to generate an electronic signal in the form of a plurality of frames
25 corresponding to the image signal;

wherein the data processing and recording device captures and analyzes the frames to quantify the radiation emitted by the biological tissue in at least one unit of measurement selected from the group including wavelength, radiance, luminosity, area, volume, temperature, change in temperature, rate of change of temperature, relative temperature, energy, change in energy, rate of change of energy, and relative energy;

wherein the data processing and recording device is further configured to control the infrared camera and the energy output of the at least one treatment radiation source to emit pulses of radiation to induce and maintain a preselected energy input to and output from the biological tissue sans the reflected energy; and

wherein the data processing and recording device is further configured to block the detection of treatment radiation reflected by the biological tissue by synchronizing the timing the emitted treatment radiation pulses with the infrared camera detection windows so that the camera captures an image of the target biological tissue at a moment between radiation pulses.

22. A method for using a therapeutic treatment apparatus for photostimulation of biological tissue, that includes the steps of:

selecting at least one treatment radiation source that provides radiation at a predetermined wavelength selected from the range approximately between 400 and 11,500 nanometers and adapted to illuminate the biological tissue;

selecting an infrared camera configured to detect infrared radiation emitted by the target biological tissue and adapted to produce image signals corresponding to the detected radiation;

selecting a data processing and recording device configured for receiving and processing the image signals and adapted to generate an electronic signal in the form of a plurality of frames corresponding to the image signals; and

capturing and analyzing the frames with the data processing and recording device;

5 and

quantifying the radiation emitted by the biological tissue in at least one unit of measurement selected from the group including wavelength, radiance, luminosity, area, volume, temperature, change in temperature, rate of change of temperature, relative temperature, energy, change in energy, rate of change of energy, and relative energy.

10

23. The method according to Claim 22, further comprising the step of controlling the energy output of the at least one treatment radiation source to induce and maintain a preselected energy input to and output from the biological tissue.

15

24. The method according to Claim 22, further comprising the step of blocking the energy emitted by the at least one treatment radiation source that is reflected by the biological tissue and subtracting the reflected energy from quantified unit of measure.

20

25. The method according to Claim 22, further comprising the step of controlling the energy output of the at least one treatment radiation source to induce and maintain a preselected energy input to and output from the biological tissue sans the reflected energy.

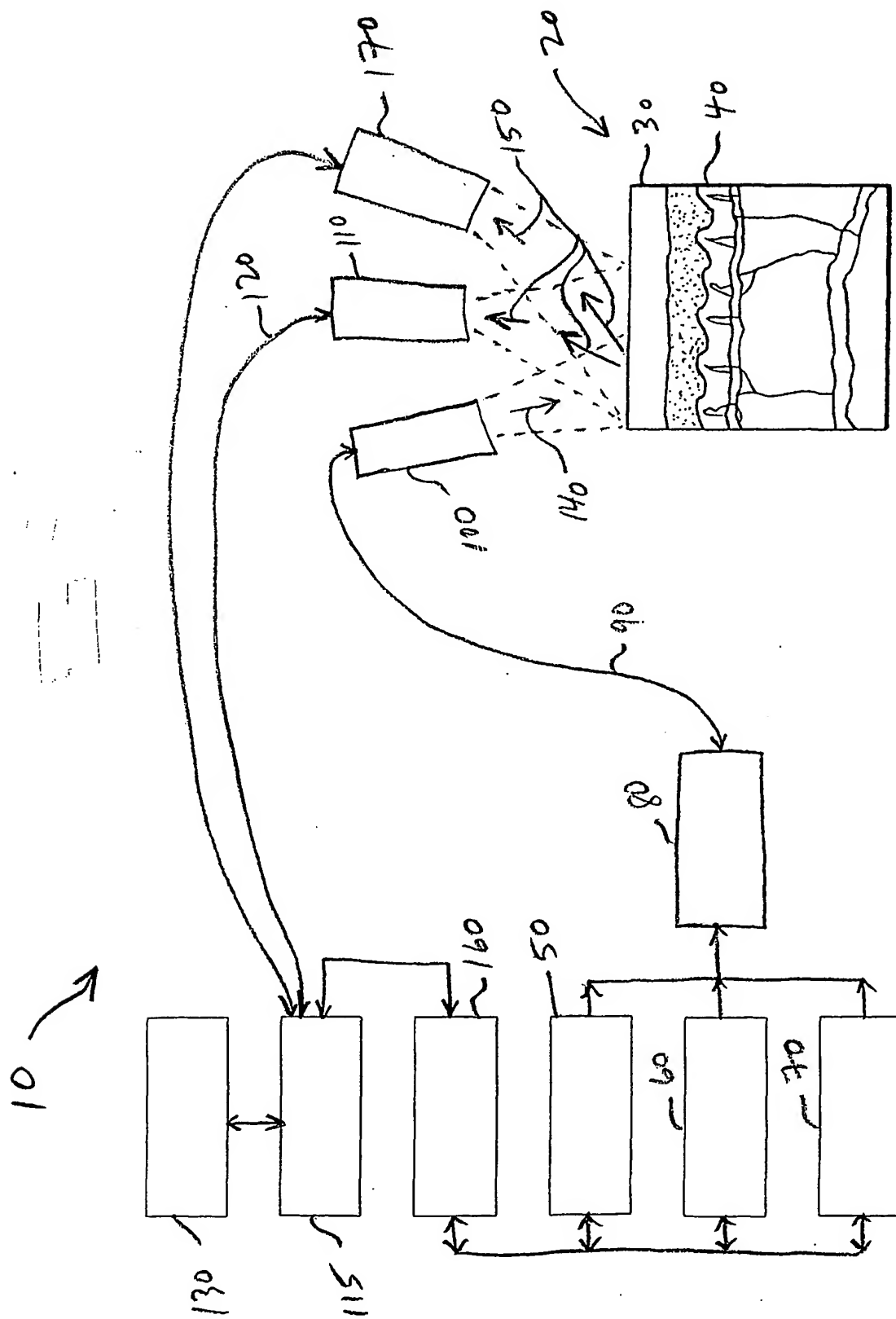


FIG. 1

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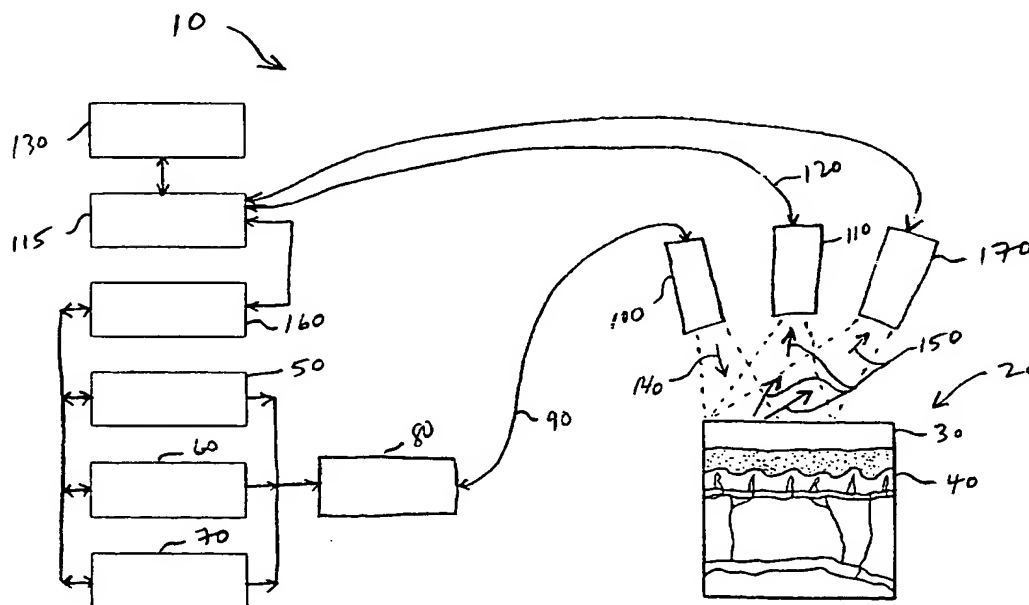
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(54) Title: **PHOTOSTIMULATON TREATMENT APPARATUS AND METHODS FOR USE**



(57) Abstract: A therapeutic treatment apparatus (10) for photostimulation of biological tissue (20, 30, 40) that includes at least one treatment radiation source (50) configured to radiate energy at a predetermined wavelength selected from the range approximately between 400 and 11,500 nanometers and adapted to illuminate the biological tissue (20, 30, 40).

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Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,860,967A (Zavislan et al) 19 January 1999, entire document.	1-4,6-7,9, 11-13,15, 20, 22-24 --- 5,8,10,14N
Y	US 5,409,481A (Poppas et al) April 1995, entire document.	5,8,10,14

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Further documents are listed in the continuation of Box C.

☐

See patent family annex.

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